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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,995	04/09/2001	Catherine A. McCall	AL-7	9579

26949 7590 07/11/2002

HESKA CORPORATION
INTELLECTUAL PROPERTY DEPT.
1613 PROSPECT PARKWAY
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EXAMINER
SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/11/2002 14

Please find below and/or attached an Office communication concerning this application or proceeding.

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EXAMINER	

ART UNIT	PAPER NUMBER
	14

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire One month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-58 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-58 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Part III: Detailed Office Action

Restriction Requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 16, 18-30, 36-54, drawn to nucleic acids, fusion proteins, expression, and kits, classified in class 435, subclass 69.1, for example.

II. Claims 11-13, 18, 31, 32, 34, 35, 51, 53, drawn to protein, classified in class 530, subclass 350, for example.

III. Claims 14, 33, 51 and 53, drawn to antibodies, classified in class 530, subclass 387.9.

IV. Claims 15 and 54, drawn to cells comprising a particular protein (not required to be recombinant), classified in class 435, subclass 325.

V. Claim 17, drawn to an immunoassay, classified in class 435, subclass 7.1.

VI. Claims 18, 51 and 53, drawn to kits or compositions comprising a nucleic acid inhibitor, classified in class 536, subclass 24.5.

VII. Claim 18, drawn to a kit comprising a protein inhibitor, classification dependent upon species.

VIII. Claims 51 and 53, drawn to a therapeutic composition comprising a mimetope, classified in class 514, subclass 2.

IX. Claims 55-59, drawn to assays for compounds that inhibit IL-13Rα1, classified in class 436, subclass 501.

X. Claim 55-59, drawn to assays for compounds that inhibit IL-13Rα2, classified in class 436, subclass 501.

Applicants are advised that some claims have been grouped with more than one invention, due to the manner in which the claims are drafted. In those cases, the claim that has been grouped with multiple inventions will be objected to for reading on multiple patentably distinct inventions, and examined only to the extent that it reads upon the elected invention.

The inventions are distinct, each from the other because:

The polypeptide of Invention II is related to the nucleic acids of Invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecules and proteins are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Inventions I, III, IV and VI-VIII are drawn to patentably distinct products, wherein each has a different structure and function which require separate searches, and wherein each is capable of separate manufacture and use.

Invention I is distinct from and unrelated to Inventions V, IX and X wherein the products of Invention I are neither made by nor used in the methods of Inventions V, IX and X, and wherein each does not require the other.

The polypeptide of Invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

Inventions II and IV are related by virtue of the fact that the cells of Invention IV comprise the protein of Invention II. However, the two are nonetheless patentably distinct, as the purified protein is not necessary for the production of the cells, and the products of the two inventions have independent means of manufacture and use.

Invention II is distinct from and unrelated to Inventions V-VIII wherein the products of

Invention I are neither made by nor used in the methods of Inventions V-VIII, and wherein each does not require the other.

Invention II and each of Inventions IX and X *may be* related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Invention II can be used in a therapeutic composition, or alternatively as an antigen for the production of antibodies.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Invention V does not specifically require the antibodies, but rather may use alternative detection techniques such as electrophoresis.

Invention III is distinct from and unrelated to Inventions IX and X, wherein the antibodies of Invention III are neither made by nor used in the methods of Inventions IX and X, and wherein each does not require the other.

Invention IV is distinct from and unrelated to Inventions V, IX and X, wherein the cells of Invention IV are neither made by nor used in the methods of Inventions V, IX and X, and wherein each does not require the other.

The methods of Inventions V, IX and X are separate and distinct, wherein each has different starting and ending points, involves different method steps, and uses or produces distinct products or results. Accordingly, each requires separate search, and restriction is proper.

Inventions VI-VIII are drawn to patentably distinct products, wherein each has a different structure and function which require separate searches, and wherein each is capable of separate manufacture and use.

The products of Inventions VI-VIII are each distinct from and unrelated to the methods of

Inventions V, IX and X, wherein the products are neither made by nor used in the, and wherein each does not require the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Further Restriction:

Regardless of which invention is elected in response to the requirement above, further restriction is required under 35 U.S.C. 121:

A. Applicants are required to elect one nucleic acid and the corresponding protein sequence from the group consisting of SEQ ID NO: 1-70, 72, 75, 78 and 81.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Election of Species:

In the event that applicants elect Invention I, above, the following election of species is required:

This application contains claims directed to the following patentably distinct species of the claimed invention: carrier proteins (a) canine IgGFc, (b) IL-13Rα1, and (c) IL-13Rα2. Each carrier protein is structurally and functionally distinct from the others, and requires a separate search of the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-9, 16, 18-30, 36-37, and 43-54 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In order to be fully responsive, Applicant must elect one from Groups I - IX, and one pair from Group A to be examined even though the requirement is traversed. Applicant is advised that neither I - X nor A are species election requirements; rather,

each of I - X, and A is a restriction requirement. In the event that Invention I is elected, applicants must further elect a single species of carrier protein. Applicants are further required to clearly point out which claims of the elected group correspond to the elected sequences and, in the case of Invention I species, as not all claims from each group read on each sequence or species.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Advisory Information:

Applicants are advised that the USPTO no longer requires recitation of sequence comparison algorithms in the text of claims. Should applicants wish to delete such information from the claims, they may do so.

Applicants are strongly urged to, when responding to this Office Action, amend the claims to limit them to the elected invention.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.

Lorraine Spector

Lorraine Spector, Ph.D.
Primary Examiner

09/828995.r
7/10/02